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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,831	12/21/2001	Paul Richard Vaughan	Q-67867	4805

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/023,831	VAUGHAN ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 31 January 2007 in response to the Final Office Action mailed 31 July 2006. Claims 31-36 were considered in the 31 July Office Action. Claims 31 and 36 were amended in the 31 January Paper. Claims 31-36 are presently pending and under consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 January 2007 has been entered.

Response to Amendments and Arguments

Claim Rejections - 35 USC § 112

Rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-36 **stand rejected** under 35 U.S.C. 102(e) as being anticipated by St. Pierre *et al.* U.S. Patent No. 5,856,308 (filed 27 September 1996) for the reasons of record and herein below in the response to Applicant's arguments.

Response to arguments

In response to the *prima facie* rejection and arguments of record, Applicant first contends that the protein of the instant claims is not anticipated by the teachings of St. Pierre et al. because, "The triple helical proteins of the present claims do not require the presence of a template bonding three proteins together to provide stability to the triple helical protein, as required by the collagen mimic disclosed in St. Pierre et al." (31 January Remarks, p. 6.)

This argument has been fully considered but is not deemed persuasive. First, the instant claims are directed to a synthetic recombinant hydroxylated triple helical protein comprising the recited elements. Therefore, the claims encompass any polypeptide having those elements and any additional elements, such as a template bonding three proteins together. Furthermore, although St. Pierre et al. teaches, "Each strand is preferably covalently linked at its C-terminal end to a template..." (col. 5, ll. 9-10) St. Pierre et al. does not teach that the template is "required" as Applicant asserts.

Next, Applicant seeks to establish that the claimed invention is not anticipated by the teachings of St. Pierre et al. by noting that the instant claims require that the polypeptide be "recombinant" and that the teachings of recombinant expression in St. Pierre et al. relates only to expression of a core domain. In particular, Applicant cites a teaching that the "collagen mimics" of St. Pierre et al. are characterized by a core comprising an ordered triple helix of at least 3 copolypeptide strands of repeating amino acid triads; cites a teaching that the core may be modified by the addition of functional groups; and cites a teaching that, if the functional group is a polymer, the polymer may be grafted onto the peptide. Applicant construes these teachings as requiring that polymers such as polyglutamic acid, poly aspartic acid and polylysine be grafted onto the core domain rather than recombinantly expressed.

This argument has been fully considered but is not deemed persuasive. Applicant's interpretation of the teachings of St. Pierre et al. is not supported by the teachings found there in considered as a whole. A teaching that a collagen mimic is "characterized by" a certain core structure is not the same as teaching that the collagen mimic "consists of" the core structure. The core domain and various additions to the core domain are all discussed under the heading "Collagen Mimics". (Col. 3, l. 61 through col. 6, l. 33.) Throughout this discussion, St. Pierre et al. refers to the core domain as, "[t]he collagen mimic core" or "[t]he mimic core" (e.g., col. 4, ll. 6 and 39). Viewed as a whole, the skilled artisan would understand that "collagen mimics" as used in St. Pierre et al. refers to the entire molecule described in section 1 under the heading "Collagen Mimics", which molecule comprises a characteristic core domain and might also comprise various other functional domains including a polymer such as polyglutamic acid, polyaspartic acid or polylysine. Therefore, references to recombinant expression of the "collagen

mimics" are reasonably understood as expression of all elements that could be produced by recombinant expression.

In the second paragraph on page 9 of the 31 January remarks, Applicant contends that the teaching at col. 6, ll. 24-34 that, "[the oligopeptide strand of the mimic] can also be prepared as fusion proteins or peptide fragments thereof from appropriate genetically-engineered expression vectors in suitable host cells" pertains only to the core domain because St. Pierre et al. refers to the oligopeptide strand of the mimic. In support of this Applicant cites col. 3, lines 37-40, wherein St. Pierre et al. refers to a "core oligopeptide structure".

This argument has been fully considered but is not deemed persuasive. The plain meaning of "oligopeptide", as the term is understood in the relevant art, is a relatively short sequence of amino acids[1]. There is no reason to believe that by referring to the core as an "oligopeptide", St. Pierre et al. intends to redefine all oligopeptides as comprising the sequence of the core, which would be contrary to the plain meaning of the term. In other words, the skilled artisan would understand the term "oligopeptide" as generic to any relatively short sequence of amino acids, including the entire amino acid sequence of a collagen mimic, comprised of both the mimic core and the additional polymer sequence. This meaning is consistent with the teaching that the oligopeptide strand of the mimic "can also be prepared as fusion proteins". (Col. 6, ll. 29-30; emphasis added.) If the oligopeptide were comprised of only a single core domain it would not be considered a "fusion protein" as that term is commonly understood in the art[2].

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[1] As opposed to a "polypeptide", which is a relatively long sequence of amino acids

[2] "Protein formed by expression of a hybrid gene made by combining two gene sequences." On-Line Medical Dictionary. Published at the Centre for Cancer Education, University of Newcastle upon Tyne © Copyright 1997-2007 - The Centre for Cancer Education. All Rights Reserved.

Furthermore, as discussed in the previous Office Action, the instant claims are directed to a product and, therefore, read on the product produced by any means. Even if, as Applicant alleges, St. Pierre is only teaching producing a core domain of repeating amino acid triads with subsequent addition of the polymer by chemical means, the ultimate product of this process, absent some evidence to the contrary, is the same as the product produced by a method wherein the entire molecule is expressed recombinantly. In other words, the recitation "recombinant" in the claims is viewed as a process limitation that defines the product only insofar as the product must be structurally the same as a product produced by the process of recombinant expression. As a polypeptide comprising a core domain of repeating amino acid triads fused to a polyglutamic acid, polyaspartic acid or polylysine as taught by Pierre et al. would be structurally the same regardless of whether it is produced by a process that involves chemical fusion or a process that involves recombinant expression of the entire protein, the polypeptide anticipates the polypeptide of the instant claims regardless of the method by which it is produced.

Next, Applicant, while acknowledging that St. Pierre et al. teaches that the polymer can be a peptide selected from polyglutamic acid, polyaspartic acid and polylysine, urges that St. Pierre et al. teaches that polymers such as polyethylene glycol are particularly suitable for clinical use. (P. 8, 3rd full ¶ through p. 9, 1st full ¶.)

This argument has been fully considered but is not deemed persuasive. As stated in the 31 July Office Action, even if St. Pierre et al. does teach some alternative embodiments as preferred, that does not negate the teaching that the polymer can be an amino acid sequence, which could be produced by recombinant means. The fact remains that St. Pierre et al. teaches synthetic hydroxylated triple helical proteins comprising polymer domains that are polyamino

acid chains, which anticipate the claimed invention irrespective of additional teachings of alternative constructs.

Finally, Applicant contends that, insofar as St. Pierre et al. suggests recombinant production of the core, the reference provides no details on how to produce the core recombinantly. In particular, Applicant contends that St. Pierre is completely silent on the need to ensure that there is hydroxylation and Applicant disagrees with the Examiner's contention that hydroxylation would be inherent.

This argument has been fully considered but is not deemed persuasive. Applicant provides no evidence that one of ordinary skill in the art would have required more guidance than what is presented in St. Pierre et al. to express a polypeptide recombinantly. In fact, in 1996 recombinant expression of collagen polypeptides was routinely practiced in the art. (See, e.g., Lamberg et al. (1996) *J. Biol. Chem.* 271:11988-11995.) St. Pierre et al. teaches embodiments wherein X_{bb} of the tripeptide repeat is hydroxyproline as most preferred. (See especially col. 4, ll. 52-53.) Given the teaching that hydroxylated prolines are most preferred the skilled artisan would recognize expression systems wherein prolines are hydroxylated as among those that are suitable. Furthermore, as St. Pierre et al. teaches a protein having the same structure as the polypeptide of the instant claims, it makes no difference whether the prolines are hydroxylated in the cell during recombinant expression or at some point after recombinant expression. What is critical to anticipation of a product is whether the art teaches a product that is structurally the same as the product claimed, not the means by which the product is produced.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §102(e) as anticipated by the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel M Sullivan, Ph.D.
Primary Examiner
Art Unit 1636